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EXAMINER	
LALLI, MELISSA LYNN	
ART UNIT	**PAPER NUMBER**
3728	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,936	MOBERG, JOHN	
	Examiner	Art Unit	
	MELISSA L. LALLI	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-11,13,19-21 and 26-29* is/are pending in the application.

4a) Of the above claim(s) *5,6,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-11,13,19-21 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This is in response to applicant's amendment wherein claims 1-3, 5, 10, 11, 13, 19, and 26 have been amended, claims 27-29 have been added, claims 5, 6, 22, and 23 have been withdrawn, and claims 12, 24, and 25 have been canceled.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

3. Claim 27 is objected to because of the following informalities: “helical disposed” as stated on line 2 should read "helically disposed". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10 and 11 are finally rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 10, the limitation “the interference fit structure includes a bead adhered to the first material” is indefinite and misleading. Is the "bead” equivalent to either of the “first portion” or "second portion" elements of claim 1? Or is the “bead” a separate element additional to the first and second portions? From fig. 6d which appears to show the “bead adhered to the first material”, there only appears to be one portion which does not have varying diameters. Is applicant mixing the different configurations shown through figs. 6a-6j? If so, there must be sufficient support in the

specification to combine the varying configurations of the interference fit structure. Furthermore, it is unclear as to what is being claimed. For examination purposes, it will be assumed that one of the first or second portions is a bead adhered to the first material; however, applicant is required to clarify and amend the claim as necessary.

Regarding claim 11, the limitation “the interference fit structures includes a first O-ring having an outer diameter and a second O-ring having an outer diameter different from the outer diameter of the first O-ring" is indefinite and misleading. Is the “first O-ring” equivalent to the “first portion” element of claim 1? Is the "second O-ring" equivalent to the "second portion" element of claim 1? Or are the first and second O-rings separate from the first and second portions? From fig. 6e, it appears that the "first O-ring" is the "first portion" and the "second O-ring" is the "second portion"; hence, the limitation will be treated as such for examination purposes. However, applicant is required to clarify and amend the claim as necessary.

Claim Rejections - 35 USC § 103

6. Claims 19-21 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,214,220 to McGlinch et al. (McGlinch) in view of US 5,217,114 to Gadberry et al. (Gadberry).

Regarding claim 19, McGlinch discloses an elongate medical device (20) suitable for packaging in a tubular member (10) having a lumen (14) defined by an inner surface, the elongate medical device comprising: an elongate shaft (22) having a proximal portion and a distal portion; a hub assembly (30) connected to the proximal portion of the elongate shaft such that the elongate shaft extends distally from the hub assembly,

the hub assembly including a portion manufactured from a first material (col. 3, lines 13-18); and a circumferential IFM (40) configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 1). McGlinch does not disclose the hub assembly including a circumferential channel and the IFM being disposed in the circumferential channel; however, Gadberry discloses a similar elongate medical device (12) suitable for packaging in a tubular member (23) with a circumferential IFM (65) disposed in a circumferential channel (64). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the circumferential channel (64) and IFM (65) arrangement of Gadberry for the IFM (40) on the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to maintain the seal when the elongate medical device is enclosed within the tubular member as taught by Gadberry.

Additionally, neither McGlinch nor Gadberry discloses the circumferential interference fit member including a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring; however, Official Notice is taken that it is old and conventional in the art to use split/gapped rings in order to facilitate application of the ring to a structure. It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring for the IFM of McGlinch and Gadberry in order to facilitate application of the IFM to the hub of the elongate medical device of McGlinch and Gadberry. The claim would have been

obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. It is inherent/obvious that the gap allows the first portion of the ring to be deflected toward the second portion of the ring when the circumferential IFM is disposed in the lumen of the tubular member since the IFM is formed of a deformable material (Gadberry; figs. 3 and 6, the IFM is readily deformable compared to the tubular member).

Regarding 20 and 21, McGlinch discloses the hub assembly (30) comprising a manifold (32) with a distal portion including the first material where the IFM is disposed about the distal portion of the manifold. A strain relief member (34) is integrally formed with the manifold (col. 3, lines 9-13).

7. Claims 1-4, 7-11, and 13 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over McGlinch in view of Gadberry and US 3,307,552 to Strawn.

Regarding claim 1, McGlinch discloses an elongate medical device (20) suitable for packaging in a tubular member (10) having a lumen (14) defined by an inner surface, the elongate medical device comprising: an elongate shaft (22) having a proximal end and a distal end, the elongate shaft extending from a proximal portion of the elongated medical device to a distal portion of the elongated medical device; a hub assembly (30) including a proximal end and a distal end, the proximal end of the elongate shaft connected to the hub assembly such that the elongate shaft extends distally from the distal end of the hub assembly, the hub assembly including at least a portion manufactured from a first material (col. 3, lines 13-18); and an interference fit structure (40) disposed about at least a part of a portion of the hub assembly including the first

material, and configured to contact and form an interference fit with an inner surface of a tubular member when the elongate shaft and the interference fit structure are disposed therein (fig. 1).

McGlinch discloses the interference fit structure (40) including a ring portion (42) and end portions (44) which have different outer diameters. It appears that the ring and end portions would allow tubular members of different diameters to connect to the hub assembly (col. 4, lines 4-18); however, if this is not apparent, Strawn discloses an elongated medical device (fig. 1) comprising a hub assembly (fig. 6) with an interference fit structure (38) including a first portion (fig. 6, first ring 38 starting from left) having an outer diameter and a second portion (fig. 6, second ring 38 starting from left) having an outer diameter different from the outer diameter of the first portion, the first portion of the interference fit structure configured to contact and form an interference fit with an inner surface of a generally tubular member (fig. 1, 12 for example) having a first inner diameter when the interference fit structure is disposed therein, and the second portion of the interference fit structure configured to contact and form an interference fit with an inner surface of a generally tubular member having a second inner diameter different from the first inner diameter when the interference fit structure is disposed therein (col. 3, lines 3-12). It would have been obvious to one having ordinary skill in the art at the time of the invention to have formed the interference fit structure of McGlinch to have first and second portions having different diameters or multiple ring portions with varying outer diameters in order to accommodate tubular members having various diameters and hence, reducing manufacturing expenses by forming one device as taught by

Strawn (col. 1, lines 38-46) instead of forming the device in a variety of sizes to engage with a specific, respective tubular member of corresponding size.

Additionally, it is unclear if the interference fit structure of McGlinch and Strawn includes a second material; however, Gadberry discloses a similar elongate medical device (12) suitable for packaging in a tubular member (23) with an interference fit structure (65) formed on a hub assembly (61) and including a second, deformable material (figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have formed the first and second portions or multiple rings of the interference fit structure of McGlinch and Strawn of the second, deformable material as taught by Gadberry in order to create a stronger frictional seal when enclosing the elongate medical device as taught by Gadberry (col. 5, lines 33-36). Furthermore, it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Regarding claim 2, McGlinch discloses the hub assembly (30) having a distal portion including a segment with a generally circular cross section including a first material (fig. 1). Gadberry discloses the interference fit structure (65) being disposed about a channel (64) extending around a segment of the hub assembly (61) including a first material, wherein at least a portion of the interference fit structure is disposed in the channel. It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the channel (64) of Gadberry on the circular segment

of the distal portion of the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to keep the seal when the elongate medical device is enclosed as taught by Gadberry.

Regarding claims 3 and 4, McGlinch discloses the hub assembly (30) comprising a manifold (32) with a distal portion including the first material where the interference fit structure is disposed about the distal portion of the manifold. A strain relief member (34) is integrally formed with the manifold (col. 3, lines 9-13).

Regarding claims 7-11, Gadberry discloses the second material being more compressible than and readily deformable compared to the first material (figs. 3 and 6). The interference fit structure is disclosed as an O-ring (col. 4, lines 25-27). Strawn provides the interference fit structure having multiple rings; hence, the first portion includes a first O-ring having an outer diameter and the second portion includes a second O-ring having an outer diameter different from the outer diameter of the first O-ring subsequent the incorporation of Gadberry to form the multiple rings of the interference fit structure into separate deformable O-rings. Either O-ring is considered a bead adhered to the first material.

Regarding claim 13, McGlinch appears to disclose the interference fit structure (40) being an elongated sleeve (42-44) having an outer circumference that varies along a length of the elongated sleeve. Strawn also discloses an elongated interference fit member (fig. 4, 30) having an outer circumference that varies along its length. Subsequent the modification in view Gadberry, the elongated interference fit structure

may be formed as an elastomeric sleeve as per the second, deformable material of Gadberry. Additionally, a change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-4, 7-11, 13, 19-21, and 26-29 are finally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,214,220 in view of Gadberry. Although the conflicting claims are not identical, they are not patentably distinct from each other because the incorporation of Gadberry renders the claims obvious as substantially the same subject mattered is recited. More specifically, it would have been obvious to one having ordinary skill in the art at the time of the invention to have formed the interference fit structure of McGlinch of the second, deformable material as taught by Gadberry in order to create a stronger frictional seal when enclosing the elongate medical device as taught by Gadberry (col. 5, lines 33-36). Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the circumferential channel (64) and interference fit member (65) arrangement of Gadberry for the IFM (40) on the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to maintain the seal when the elongate medical device is enclosed within the tubular member as taught by Gadberry.

Response to Arguments

10. Applicant's arguments with respect to claims 1-4, 7-11, 13, and 19-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Luther, Gaba, Haselhorst et al., and Cianci et al. have been included because they are relevant to the claimed subject matter.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA L. LALLI whose telephone number is

(571)270-5056. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLL
3/29/10

/JILA M MOHANDESI/
Primary Examiner, Art Unit 3728